Testimony of the Cannabis Standards Institute

Concerning the Distribution of Medical Marihuana in Michigan

House Judiciary Committee, Lansing
9:00 a.m., May 23, 2013

Good Morning, I am Richard Fitzpatrick and I am the President of the *Cannabis Standards Institute (CSI)*. We were formed on the belief it should be self-evident that where medical cannabis is legal and regulated; patients deserve access to pharmaceutical grade medicine that is labeled with accurate, useful and independently-verified information.

We compliment the Chair of this Committee on the open-ended topic of today's hearing and offer this testimony with the intent of helping the State of Michigan finally, responsibly, implement the will of the public as expressed in the general election of 2008.

CSI supports, in principle, HB 4271 as a vastly improved method for distributing medical marihuana in Michigan. We applaud its creation of "Safety Compliance Facilities" but are deeply concerned there are no requirements that they actually be used or even that safety be complied with at all. It explicitly exempts "Provisioning Centers" and the products they sell, from all state and local health and safety regulations {Sec 6. (2)}.

It is disconcerting that the bill does not establish any standards or accreditation for a business to call itself a "Safety Compliance Facility" - nor is the application and approval process defined. If licensing is left solely to local units of government, that would mean any business that convinces one township, village or city that it should be considered a "Safety Compliance Facility" -- it would then be authorized to act as such throughout the entire state.

We respect all that Rep Mike Callton is doing to see that registered users of medical cannabis obtain products of high quality and safety that meet their unique medical needs. We would like to add these two key points plus an amendment for your consideration.

- **There are established, widely-accepted and available safety tests for medical marihuana.**

When cannabis is used as an herbal remedy, it can be treated as any other natural, herbal supplement. The processes and standards for testing the flowers of cannabis for impurities are no different than the processes and standards for testing the

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flowers of hops or chamomile. The procedures for safely extracting oil from cannabis are no different than for extracting oil from flax or evening primrose.

The Federal Drug Administration (FDA) spent more than seven years in a comprehensive, inclusive process before issuing the Final Rule *"Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements."* Those established standards are as valid for measuring the safety and purity of cannabis as they are for any other botanical product.

In addition, laboratories with specific experience in testing cannabis are found in many US states, provinces of Canada, the Netherlands, Israel and elsewhere.

The initiation of the legal sale of medical marihuana in Michigan by retail "Provisioning Centers" should be accompanied by requirements for an assurance of purity, consistency of dosage and full disclosure of active ingredients.

- **Unbiased, third-party analytical testing is essential.**

To protect the public health, bottled water from water sources originating in Michigan must be frequently sampled and tested by commercial third-party labs approved by the state's Department of Environmental Quality and labeled with the test results. *{Michigan Food Law of 2000 MCLA 289.7111}.*

Shouldn't medical marihuana patients be protected in the same way against potential harm caused by unsafe or adulterated processing and packaging?

Michigan does not allow a product to be labeled as "organic" unless it has been certified by an independent, third-party as having been organically grown, produced, processed, and manufactured according to accepted standards.

It is not sound public policy to allow a medical product to be sold untested or based only on the in-house DIY analysis by a Provisioning Center itself.

All of the states currently establishing rules for regulated marihuana distribution are requiring independent laboratory testing.

To provide this kind of independent validation, the law approved by the voters in the State of Washington last November allowing all adults the ability to purchase marihuana, requires all "useable marijuana, or marijuana-infused products produced or processed by the licensee be submitted to an independent, third-party testing laboratory for inspection and testing of batches no larger than 2 pounds to certify compliance with standards adopted by the state..."

The similar amendment adopted in Colorado creates four distinct licensed "marijuana establishments." Along with Cultivation, Product Manufacturing and Retail Store, there is ***Marijuana Testing Facility*** "which means an entity licensed to analyze and certify the safety and potency of marijuana." And the first three are not allowed to have any financial interest in a testing facility.

Massachusetts and Connecticut, which are both currently promulgating regulations for distribution of pharmaceutical grade medical marihuana, require a random sample of every batch be tested by an independent laboratory "for microbiological contaminants and chemical residue, and for purposes of conducting an active ingredient analysis."

Registered marihuana patients should be able to rely on regulators and governments to rigorously and impartially ensure that cannabis and its packaging are safe and that producers are being held to account for their practices. That means requiring independent, third-party testing immediately prior to final packaging.

Based on the belief that all medicine should be labeled with accurate, useful and independently-verified information, we recommend that the requirements in HB 4271 {Sec 7 (4)} should be strengthened:

1. All marihuana and marihuana products dispensed should be completely and properly labeled. This means striking "a marihuana-infused product for use as" {page 9; line 19}; and, on the next line {20}

2. Striking "both of" and replace items (a) and (b) with:

a) The provisioning center's name, address and telephone number;
b) A unique serial number and/or bar code that will match the product with a provisioning center's batch so as to facilitate any warnings or recalls;
c) The date of dispensing the marihuana;
d) The quantity of marihuana dispensed;
e) The name of the qualifying patient and, where applicable, the registered primary caregiver;
f) The words - "WARNING: This contains marihuana. For a qualifying patient's medical use only." or substantially similar text;
g) The name of the certifying physician;
h) Such directions for the type of cannabis to be dispensed and any instructions for its use as may be included in the physician's written certification or otherwise provided by the physician;

i) A Safety Certification based on an active ingredients analysis from a Safety Compliance Facility which reports:
1) All active ingredients that constitute at least one (1) wt. % of the marihuana in the product, to always include:
(i) DELTA 9-TETRAHYDROCANNABINOL (THC);
(ii) CANNABIDIOL (CBD);
2) A pass/fail rating based on a microbiological analysis that was completed immediately prior to final packaging;
3) A pass/fail rating based on a chemical residue analysis that was completed immediately prior to final packaging; and
4) Name and place of business of the Safety Compliance Facility where tested and date final analysis was completed.

j) Such other information necessary to comply with state or local labeling requirements for similar products not containing marihuana, including but not limited to the Michigan Food Law (PA 92 of 2000, as amended); Michigan's Cottage Food Law (PA 113 of 2010, as amended);and the Michigan Modified Food Code.

k) Labels must be printed on, or securely attached to, any package containing marihuana or a marihuana product. All marihuana and marihuana products shall be dispensed in a sealed, tamper-evident container or packaging. It should be opaque and comply with the definitions and the requirements of the Poison Prevention Packaging Act of 1970, 15 U.S.C. sections 1471 to 1476.

l) A Provisioning Center shall develop, document, and implement policies and procedures regarding patient education and support, including:

1) Availability of different chemotypes of marihuana and the purported effects of the different chemotypes;
2) Information about the purported effectiveness of various methods and forms of medical marihuana administration; and
3) Method for tracking the effects on a qualifying patient of different chemotypes and forms of marihuana.

m) All marihuana and marihuana products shall be processed, tested, packaged and labeled according to the US Food and Drug Administration's *"Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements"* Rule.

The right to information is a core platform of individual consumer rights. We know that cannabis, itself, is safe and wholesome. Still, individuals should be protected against harm caused by unsafe or adulterated growing, processing & packaging. Labeling should provide patients with accurate information that is sufficient to enable them to make well-informed choices.

In conclusion, if you are purporting to create a system for the responsible distribution of medical marihuana, then of course you must insure a supply of a medicinal grade product with all the purity and freedom from contaminants, both chemical and biological, which is implied by the use of "medical" in describing marihuana.

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